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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,329	11/09/2001	Michael Baudino	11738.00050	4048

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MEDTRONIC, INC.
710 MEDTRONIC PARKWAY NE
MS-LC340
MINNEAPOLIS, MN 55432-5604

EXAMINER

HAYES, MICHAEL J

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SN

Office Action Summary	Application No.	Applicant(s)	
	10/053,329	BAUDINO ET AL.	
	Examiner	Art Unit	
	Michael J. Hayes	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 80-135 is/are pending in the application.
- 4a) Of the above claim(s) 110-135 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 80-109 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 November 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/26/03, 2/24/03</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 80-109, drawn to an agent delivery system including a therapy delivery device, classified in class 604, subclass 131.
- II. Claims 110-113, and 120-135, drawn to a delivery system including first and second catheters with a first liquid in the first catheter and a second liquid in the second catheter, classified in class 604, subclass 264.
- III. Claims 114-117, drawn to a delivery system including a first catheter extending from an opening of a cannula at a first angle, classified in class 604, subclass 95.04.
- IV. Claims 118-119, drawn to a delivery system including an inner catheter and a plurality of outer catheters arranged around the inner catheter, classified in class 604, subclass 27.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III, and IV are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, the inventions have separate utility such as delivery systems not requiring the elements of the other inventions as discussed above. See MPEP § 806.05(d).

Art Unit: 3763

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Binal Patel on 1/13/05 a provisional election was made to prosecute invention I, claims 80-109. Affirmation of this election must be made by applicant in replying to this Office action. Claims 110-135 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Applicant did not state whether the election was made with or without traverse. Applicant should state in his next response whether the election is with or without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the cannula having plural openings in the lumen distal end with first and second catheters protruding as claimed in claim 1, the delivery device connected to a first catheter through a first catheter port to a second catheter through a second catheter port as recited in claim 85, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Art Unit: 3763

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 80-102 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

Art Unit: 3763

art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not describe various limitations recited in the new claims 80-109. It appears that these limitations are new matter: catheter protruding from the cannula as recited in claim 80, the delivery device coupling through ports as recited in claim 85, the treatment of various diseases/conditions as recited in claims 87, 88, 108, 109, determining liquid infusion rate through first and second catheters with a parameter and signal level as recited in claim 91, use of parameters and settings to control liquid infusion as recited in claims 92-98, and the sensor in the proximity of liquid delivery position as recited in claim 104.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: there is no antecedent basis in the specification for setting as used in claims 95-98.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

Art Unit: 3763

subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 80, 81, 82, 83, 85-89, 103, 107-109 are rejected under 35 U.S.C. 102(e) as being anticipated by GILLIS et al. (US Publication No. 2003/0069541). Gillis discloses a delivery system having first and second catheters 60 protruding from a multiple opening cannula 10 and a therapy device (50 and hub) that couples to the first and second catheters. Gillis discloses that the use of replenishment ports is well known in the art to allow for injection of additional drug [0008]. Fig. 4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 80, 81, 85, 86, 87, 88, 89, 90, 103, 107-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over HOWARD, III (US Patent No. 6,129,685). Howard discloses a delivery system with first and second catheters extending from a cannula to deliver a drug and a pump that supplies the liquid medication in the embodiment shown in fig. 30. In this embodiment Howard does not show a plurality of openings in the cannula. In the embodiment shown in figs. 23 and 25 Howard shows a plurality of openings to direct drug delivery to different locations. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of the embodiment shown in figs. 23 and 25 in the embodiment shown in fig. 30 to treat different areas of a patient.

Art Unit: 3763


Claims 82-84, 91-102, and 104-106 are rejected under 35 U.S.C. 103(a) as being unpatentable over HOWARD, III in view of ELSBERRY et al. (US Patent No. 5,711,316). Howard discloses the claimed invention except for the port, sensor and processor control of the infused liquid from the pump, and timer. Elsberry discloses these limitations to facilitate the delivery of the correct dosing of drug for treating a patient. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Elsberry in the system of Howard to appropriately administer medication to treat a patient.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi, can be contacted at (703) 308-2698. The fax number for submitting official papers is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh
19 January 2005


MICHAEL J. HAYES
PRIMARY EXAMINER